

### **REMARKS**

This paper responds to the Office Action of March 30, 2010, which was made final and in which the Examiner rejected claims 1-21 and 36-40 under 35 U.S.C. § 103(a).

By this paper, claims 1, 18, 36, 37 and 38 have been amended. No new matter has been introduced.

Reconsideration and allowance are requested.

#### **Examiner Interview**

The August 24, 2010 Examiner Interview between Examiner Pritesh Patel and Bridget Hayden is appreciated. During the interview, proposed claim amendments to the independent claims were discussed. Pursuant to the interview, it is believed that upon submission of the amendments of this paper, the present application will be in condition for allowance and all outstanding issues will be resolved. If the Examiner believes further discussion or an Examiner's amendment will result in allowance of the claims, he is invited to contact the undersigned or Bridget Hayden at (612) 492-6867.

#### **Rejections under 35 U.S.C. § 103(a)**

Claims 1-21 and 36-40 were rejected under 35 U.S.C. § 103(a) as unpatentable over US Patent 5,226,895 (Harris) in view of US Patent 6,582,408 (Buch-Rasmussen). The Examiner's position is traversed for at least the following reasons.

Independent claim 1 has been amended to clarify that the at least one axial guide comprises a channel extending parallel to a longitudinal axis of the administering apparatus, the channel on one of the casing sections, and a rib extending parallel to the longitudinal axis and shaped to complement at least a portion of the channel, the rib on the other of the casing sections, such that when the casing sections are being connected by being slid together they are guided linearly along the longitudinal axis by an engagement between the channel and the rib as far as a connecting end position, said engagement preventing the casing sections from rotating relative to each other about said rotational axis during the linear guiding and at the connecting end position,

which prevents transmitting rotational movements onto the driven member and the dosage setting member. The claim amendments are supported at least at paragraphs [0017], [0019] and [0098] and FIG. 11 of US 2004/0186441 (the publication of the instant application).

The Examiner asserts that Harris discloses all of the elements of the claimed administering apparatus but for the axial guide, and turns to Buch-Rasmussen for remedying this fundamental disclosure deficiency. *Office Action*, page 2.

Actually, Harris discloses a housing 12 and two cap portions 86 and 100, which the Examiner characterizes as the claimed front casing section and rear casing section. In Harris, “[t]he two cap portions 86 and 100 can be bonded by a conventional means such as ultrasonic welding or solvents or the like. The assembly is then pushed inside housing 12 until barrier element 108 is situated at the location 116 shown in phantom. The barrier element 108 is then fixed to the housing 12 again using solvents . . . .” *Harris*, column 5, lines 31-38. Because Harris does not disclose the housing 12 and cap portions 86 and 100 include axial guides for guiding assembly, the Examiner looks to Buch-Rasmussen and asserts the “means for coupling the dosing assembly and the cartridge assembly together” disclosed in Buch-Rasmussen render the independent claims obvious. *Office Action*, pages 2-3.

However, Buch-Rasmussen does not address the fundamental disclosure deficiencies of Harris in relation to independent claim 1, as amended. Buch-Rasmussen describes the medication delivery device shown in the drawings has having “dosing assembly [that] comprises coupling means 8 adapted for engagement with the cartridge assembly” (*Buch-Rasmussen*, column 4, lines 41-45) and each of the figures depicts threading for rotationally establishing an engagement between the coupling means 3 of the cartridge assembly 1 and the coupling means 8 of the dosing unit 6. Indeed, the reference discloses “when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, *such as through a threaded coupling* . . . .” In fact, Buch-Rasmussen discloses “preferred combinations of coupling between the dosing assembly and the cartridge assembly . . . [is] a threaded coupling . . . .”

While Buch-Rasmussen discloses a variety of means for coupling the dosing assembly and the cartridge assembly together, see column 3, lines 8-13, it does not disclose the axial guide of amended claim 1. That is, Buch-Rasmussen does not disclose or suggest the structure of a channel in combination with a rib. Nor does the reference disclose or suggest the function of the axial guide and engagement element in which the engagement between the two prevents the casing sections from rotating during linear guiding and at the connecting end position. Such an engagement prevents transmitting rotational movements onto the driven member and the dosage setting member. The specification of the present application states:

Sliding the casing sections onto each other, axially and linearly guided, makes assembling the apparatus particularly simple. Furthermore, when establishing the coupling between the dosing and activating device and the driven member and the dosage setting member, it prevents unintentional rotational movements of the casing sections relative to each other from transferring undesirable rotational movements onto the driven member and/or the dosage setting member, wherein said rotational movements could cause a dosing movement of the dosage setting member, even if only due to response movements of the dosing and activating device to such unintentional rotational movements between the casing sections. *US 2004/0106441*, para. [0017].

Because neither Harris nor Buch-Rasmussen provide any disclosure of a linear guide or advantages of a linear guide as described above, the references, viewed alone or in combination, do not disclose or suggest the axial guide and engagement element in the manner of independent claim 1, as amended.

Further, the Examiner mischaracterizes the Buch-Rasmussen column 3, lines 8-14 disclosure by asserting that the reference discloses “a series of mechanisms including bayonet locks, long protruding elements that can axially align two casings.” *Office Action*, pages 2-3. Buch-Rasmussen does not disclose any specific bayonet lock structure, and clearly does not disclose the axial guide and engagement element as claimed. If the Examiner believes bayonet locks are relevant to the claimed invention, and the Examiner repeats the rejection on this basis, the Examiner is invited to take official notice of what the Examiner believes is well known in the art. However, in taking official notice, the Examiner is reminded that:

[i]t would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of

instant and unquestionable demonstration as being well-known .... The facts constituting the state of the art are normally subject to the possibility of rational disagreement among reasonable men and are not amenable to the taking of such notice. *MPEP §2144.03 (underlining in original)*.

For at least the foregoing reasons, amended independent claim 1 is not rendered obvious by the asserted combination of Harris and Buch-Rasmussen.

Claims 2-21 and 39-40 depend directly or indirectly from amended independent claim 1 and are patentable for at least the reasons set forth above, further in view of their additional recitations.

Independent claim 36 was rejected on the same grounds as claim 1 and has been amended to recite the channel and rib. According to amended claim 36, one of the axial guide or the engagement element is provided on the front casing section and the other on the rear casing section, which:

enable[s] sliding and linear guiding along the longitudinal axis by an engagement between the axial guide and the engagement element such that the front casing section and the rear casing section of the administering apparatus are secured against rotating and guided onto each other as far as a connecting end position, said engagement preventing the casing sections from rotating relative to each other during the linear guiding and at the connecting end position.

For the reasons set forth above in connection with claim 1, Harris in view of Buch-Rasmussen does not disclose or suggest the structure of the axial guide channel in combination with the engagement element rib, nor do the combination of references disclose the function of the engagement preventing the casing sections from rotating during linear guiding and at the connecting end position.

Claim 36 has also been amended to recite that “the front casing section comprises a first latching element and the rear casing section comprises a second latching element and the latching elements axially fix the casing sections onto each other in a releasable latching engagement upon the casing sections reaching the connecting end position.”

The combination of Harris and Buch-Rasmussen does not disclose or suggest the above recitation of claim 36 because, in Harris, the cap portions 86 and 100, which are likened to the claimed rear casing portion, and particularly cap 72 of cap portion 86:

includes a radially projecting tang 94 which interacts with a grooved interior of housing 12. The tang 94 functions to provide an audible and tactile indication of the amount or degree of rotational movement of cap 72 with respect to housing 12. The tang 94 also aids linear movement of cap 72 with respect to housing 12 under the application of a force normal to the proximal end 98 of cap 72. *Harris*, column 4, lines 28-35.

Harris explains that during dosing, rotation of cap 72 “would back the distal end 84 of the proximal cap portion 86 away from stop shoulder 48 on the inside of housing 12.” *Harris*, column 4, lines 43-45. Therefore, Harris relies on rotation and axial movement of cap portion 86 for dosing. Even if the teachings of Buch-Rasmussen could be incorporated with the teachings of Harris, such a combination would not yield the invention of claim 36 wherein the “latching elements axially fix the casing sections onto each other in a releasable latching engagement upon the casing sections reaching the connecting end position.” Trying to achieve this by modifying Harris as suggested by the Examiner would make the dosing mechanism of Harris inoperable.

Independent claims 37 and 38 were rejected on the same grounds as claim 1 and have been amended to recite one of the front and rear casing sections includes a channel and the other casing section includes a rib. According to claims 37 and 38, when the casing sections are slid together they are guided linearly by the engagement between the channel and the rib as far as a connecting end position, the engagement preventing the casing sections from rotating relative to each other during the linear guiding and at the connecting end position.

For at least the reasons set forth above in connection with claim 1, Harris in view of Buch-Rasmussen does not disclose or suggest the claims 37 and 38 recited structure of the axial guide channel in combination with the engagement element rib, nor does the combination disclose the function of the engagement preventing the casing sections from rotating during linear guiding and at the connecting end position.

Claims 37 and 38 have also been amended to recite latching elements. As discussed above in connection with amended independent claim 36, Harris relies on rotation and axial

movement of cap portion 86 for dosing. With respect to claims 37 and 38, even if the teachings of Buch-Rasmussen were incorporated with the teachings of Harris, such a combination would not yield latching elements that axially fix the casing sections onto each other in a releasable latching engagement when the casing sections reaching the connecting end position. If this were tried, the dosing mechanism of Harris would be inoperable.

**Conclusion**

In view of the foregoing, reconsideration and withdrawal of the §103 rejections are requested.

This paper is being submitted on or before August 30, 2010, and an extension of the time to respond until that date is requested. The required fee should be charged to Deposit Account No. 04-1420. No additional fees should be due in connection with this paper, but the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

The application now stands in allowable form, and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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